REMARKS

Claims 52-55 are pending following entry of the Amendment above. Claims 52 and 53 have been amended to more particularly point out the features of the present invention. The claims stand rejected for indefiniteness and for obviousness. The outstanding rejections are addressed below.

Interview Summary.

The Applicants appreciate the time and courtesy extended toward Applicants' representative, Karen Magri, during the telephonic interview on September 14, 2005. During the interview the meaning of the term "marine oil" and the language of claim 52 was discussed.

Indefiniteness.

Claims 52-55 stand rejected under 35 U.S.C. §112, second paragraph for indefiniteness. First, the Office Action states that the term "about" is unclear. The Applicants respectfully disagree with this rejection, but have amended claims 52 and 53 to omit the term "about" in order to expedite the prosecution of this application to allowance.

Claims 52-55 further stand rejected for reciting "marine oil." Specifically, the Office Action states that the term "'marine oil' is not clearly defined in the specification but merely gives one example, eicosapentaenic acid (EPA) is a marine oil." Applicants respectfully disagree with this rejection.

As discussed during the telephone interview, the term "marine oil" is understood by those skilled in the art. United States Patent Nos. 5,747,533 (*see, e.g.*, claim 2) and 5,346,709 (*see, e.g.*, claim 1), which are entitled to a presumption of validity, are exemplary of the numerous patents that use the term "marine oil" and are evidence that the "metes and bounds" of this term are well understood by those of ordinary skill in the art (copies of these patents are enclosed herewith).

Further, the Applicants respectfully point out that eicosapentaenic acid (EPA) is not a marine oil. EPA is an essential polyunsaturated omega-3 fatty acid, which is known to be present in marine oil. During the telephone interview, the Examiner requested that Applicants enclose evidence that marine oil contains EPA. Applicants are enclosing herewith two articles from the internet describing the relationship of EPA to fish oil ("Fish oil is the natural anti-cholesterol agent", www.naturalelixir.com/fishoil.html; "Good fat, bad fat: the facts about Omega-3", http://mywebmd.com/content/article/91/101125.htm). In addition, the present specification states at page 14, lines 16-17, that "EPA may be found in marine oils and various algal and fungal oils."

In addition, contrary to the assertion in the Office Action, EPA is not the only essential fatty acid found in fish oil that is disclosed in the application. The application also discloses docosahexanoic acid (DHA) at page 6, lines 26-27. DHA is known in the art to be an essential polyunsaturated omega-3 fatty acid that is found in marine oils (*see, e.g.*, internet articles cited above).

Finally, the outstanding obviousness rejection states that the cited DeMichele et al. reference "discloses that fish oils (one of marine oils) are well known to contain eicosapentaenoic acid (EPA)." Thus, the present Office Action concedes that the term "marine oil" is understood in the art and, further, that it is known that marine oil contains EPA.

The Office Action also states that "[g]iven the fact that not any 'marine oil' is safe to be administered to a human or an animal." The Office Action does not explain how this comment is related to the outstanding indefiniteness rejection and no objective evidence is provided that marine oils are, in fact, unsafe. In the absence of any such evidence, the outstanding rejection cannot be maintained on this basis.

As discussed during the interview, claim 52 has been amended to recite "wherein the oils are (i) concentrated borage oil and (ii) concentrated marine oil that contains eicosapentaenic acid." This language is supported by the specification in the table at page 45, Example 11, which describes a

dietary fatty acid supplement comprising concentrated marine oil containing EPA.

Applicants submit that those ordinarily skilled in the art would have been familiar with the term "marine oil," would have known that EPA is an essential polyunsaturated omega-3 fatty acid, and would have been aware that marine oils contain EPA both from the teachings of the specification and the knowledge in the art as a whole. Accordingly, the language of claims 52-55 is sufficiently definite and satisfies the requirements of 35 U.S.C. §112, second paragraph, and Applicants respectfully request that the outstanding rejection on this basis be withdrawn.

Obviousness Rejection.

Claims 52-55 stand rejected under 35 U.S.C. §103(a) for allegedly being obvious over U.S. Patent No. 5,223,285 (DeMichele et al.) in view of EP 0 782 827 (Igarashi et al.) and U.S. Patent No. 4,154,863 (Kahn et al.). Applicants respectfully traverse this rejection below.

The Office Action states that Bled C in Table 2 (col. 9, lines 32-65) of DeMichele et al. describes a nutritional composition comprising 40% borage oil and marine oil by weight. The Office Action further states that Igarashi et al. teaches that glycerin is a known food additive, and Kahn et al. teaches that minor ingredients such as xanthan gum, colorant sorbic acid, and palmitate are known for use in nutritional or food compositions. The Office Action concludes that one of ordinary skill in the art "would have been motivated to optimize the effective amounts of active ingredients in a nutritional composition or a food composition because the optimization of known effective amounts of known ingredients is considered well within conventional skills in food and nutritional science or industry, involving merely routine skill in the art."

The outstanding rejection amounts to an argument that the combination of known ingredients cannot result in a patentable food or nutritional product. This position is clearly not supported by the law. The

relevant issue is whether the cited art provides any suggestion or motivation to one of ordinary skill in the art to modify or combine the teachings of the cited references to arrive at the claimed invention, and further whether the cited art provides a reasonable expectation of success with respect to the claimed invention. No such motivation or reasonable expectation is found in DeMichele at al. or the cited secondary references. The present claims are drawn to a liquid dietary supplement consisting essentially of specified ingredients. One of ordinary skill in the art would have had no reason to modify the composition of DeMichele et al. to arrive at the presently claimed dietary supplement based on DeMichele et al. alone or in combination with Kahn et al. and Igarashi et al.

The nutritional composition represented by Blend C in Table 2 of DeMichele et al. comprises PULMOCARE®, which is a high fat/low carbohydrate enteral composition formulated for patients with chronic obstructive pulmonary disease or acute respiratory formula, which is further supplemented with fish oil and borage oil. PULMOCARE® itself contains canola oil, corn oil, high oleic safflower oil and medium chain triglyceride (MCT) oil. The list of ingredients in PULMOCARE® is enclosed herewith. Thus, the oil composition of the diet of DeMichele et al. is readily distinguished from the oils in the presently claimed dietary supplement.

The Office Action argues that Table 2 of DeMichele et al. discloses a nutritional composition containing 40 weight percent of fish oil and borage oil. Applicants respectfully point out that this is a misreading of Table 2. Table 2 shows the composition of the lipid blend in the PULMOCARE® based diet. Borage oil and fish oil make up 40% by weight of the lipid blend, not 40% by weight of the nutritional composition. As is apparent from evaluating the composition of PULMOCARE® and the nutritional composition described in Table 7 of DeMichele et al., fish and borage oil account for less than 4% by weight of fish and borage oils and less than 12% by weight in total oils in the nutritional compositions taught by DeMichele et al.

Further, the diet of DeMichele et al. has a low carbohydrate content. The low carbohydrate content is designed to reduce carbon dioxide production so as to minimize the carbon dioxide retention characteristic of pulmonary disease (*see, e.g.*, col. 9, lines 34-38). Both the nutritional composition containing the Blend C oil blend in Table 2 (see composition of PULMOCARE®) and the composition in Table 7 of DeMichele et al. contain 10.28 weight percent carbohydrate. In contrast, the present claims recite "25 weight percent sucrose." One of ordinary skill in the art would not have had any motivation to formulate a dietary supplement comprising 25% weight percent sucrose based on the teachings of a low carbohydrate diet for treating pulmonary disease in DeMichele et al.

The deficiencies of the DeMichele et al. reference cannot be remedied by combination with Igarashi et al. and Kahn et al. which also fail to disclose or suggest the presently claimed dietary supplement.

In view of the foregoing, Applicants respectfully submit that the dietary supplement recited by claims 52-55 is not obvious in view of DeMichele et al. in combination with Igarashi et al. and Kahn et al., and respectfully request that the outstanding rejection on this basis be withdrawn.

Conclusion.

The concerns of the Examiner having been addressed in full, Applicants respectfully request withdrawal of all outstanding rejections and the issuance of a Notice of Allowance forthwith. The Examiner is encouraged to address any questions regarding the foregoing to the undersigned attorney, who may be reached at (919) 854-1400.

Respectfully submitted,

Karen A. Magri
Registration No. 41,965

Enclosures:
U.S. 5,747,533
U.S. 5,346,709
Internet articles
PULMOCARE™ product information

Customer No. 20792
Myers Bigel Sibley & Sajovec, P.A.
P. O. Box 37428
Raleigh, North Carolina 27627
Telephone: (919) 854-1400
Facsimile: (919) 854-1401

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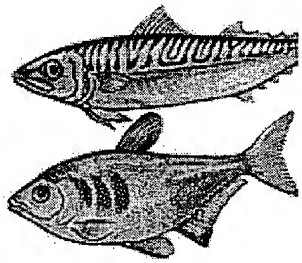
Katie A. Chung

french paradox, red wine, heart protector, heart disease, free radicals, antioxidants

FISH OIL is the Natural Anti-holesterol agent

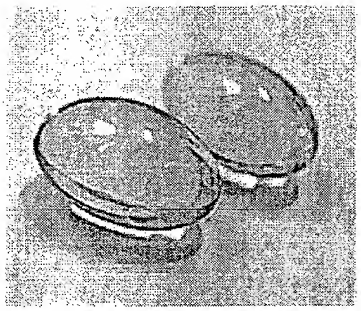


Fish oil capsules contain oil derived from herbivorous fish species (mackerel, salmon, sardine) living in the deep, cold waters of the Atlantic and Pacific oceans, then purified and cryo concentrated.

The major active ingredients of fish oil are two essential polyunsaturated so-called omega-3 fatty acids: EPA (eicosapentaenic acid) and DHA (docosahexaenic acid), which cannot be produced by the human organism. Alpha-linolenic acid can be converted to EPA and DHA in the body, but the conversion is quite inefficient especially in older people. The administration of these polyunsaturatec acids as treatment courses lowers blood lipid and cholesterol levels, improves the rheological propei the blood and exerts a favorable effect on blood coagulation process.

Fish oils (EPA and DHA) play a crucial role in the prevention of atherosclerosis, heart attack, depres and cancer.

Recognizing the unique benefits of EPA and DHA and the serious consequences of a deficiency the U National Institutes of Health recently published Recommended Daily Intakes of fatty acids. They recommend a total daily intake of 650 mg of EPA and DHA, 2.22 g/day of alpha-linolenic acid and 4. g/day of linoleic acid. Saturated fat intake should not exceed 8 per cent of total calorie intake or abc g/day.



The US National Institutes of Health recently published Recomme Daily Intakes of fatty acids.

EPA and DHA	**- 650 mg/day**
Alpha-linolenic acid	**- 2.22 g/day**
Linoleic acid	**- 4.44 g/day**

Saturated fats - should not exceed 8 percent of total calorie intak about 18 g/day.

Good for the brain and children too

The human brain is one of the largest "consumers" of DHA. A normal adult human brain contains m than 20 grams of DHA. Low DHA levels have been linked to low brain serotonin levels which again a connected to an increased tendency to depression, suicide, and violence. A high intake of fish has b linked to a significant decrease in age-related memory loss and cognitive function impairment and a risk of developing Alzheimer's disease. A recent study found that Alzheimer's patients given an ome rich supplement experienced a significant improvement in their quality of life.

Several studies have established a clear association between low levels of omega-3 fatty acids and depression. Other studies have shown that countries with a high level of fish consumption have few cases of depression.

An adequate intake of DHA and EPA is particularly important during pregnancy and lactation. Durinç time the mother must supply all the baby's needs for DHA and EPA because it is unable to synthesiz these essential fatty acids itself. DHA makes up 15 to 20% of the cerebral cortex and 30 to 60% of retina so it is absolutely necessary for normal development of the fetus and baby. There is some ev

that an insufficient intake of omega-3 fatty acids may increase the risk of premature birth and an abnormally low birth weight. There is also emerging evidence that low levels of omega-3 acids are associated with hyperactivity in children.
Experts recommend that women get at least 500-600 mg of DHA every day during pregnancy and lactation. The easiest way to ensure this intake is to take a good fish oil supplement daily.
Children who regularly eat fresh, oily fish have a four times lower risk of developing asthma than dc children who rarely eat such fish. They speculate that EPA present in the fish may prevent the development of asthma or reduce its severity by reducing airway inflammation and responsiveness. Supplementation with 3.3 grams/day of fish oil markedly reduces breathing difficulties and other symptoms in asthma patients.

The heart's best friend
An enormous amount of medical literature testifies to the fact that fish oils prevent and may help to ameliorate or reverse atherosclerosis, angina, heart attack, congestive heart failure, arrhythmias, st and peripheral vascular disease. Fish oils help maintain the elasticity of artery walls, prevent blood clotting, reduce blood pressure and stabilize heart rhythm.
Fish oil supplementation may help prevent arrhythmias and sudden cardiac death in healthy men. A Italian study of 11,000 heart attack survivors found that patients supplementing with fish oils mark reduced their risk of another heart attack, a stroke or death. A group of German researchers found fish oil supplementation for 2 years caused regression of atherosclerotic deposits and American mec researchers report that men who consume fish once or more every week have a 50% lower risk of c from a sudden cardiac event than do men who eat fish less than once a month.
Fish oil supplementation (10 grams/day) reduces the number of attacks by 41% in men suffering fr angina and the severity of a heart attack
Fish oils are especially important for diabetics who have an increased risk of heart disease.

Reduces pain and helps prevent cancer
Fish oils are particularly effective in reducing inflammation and can be of great benefit to people suf from rheumatoid arthritis or ulcerative colitis. Daily supplementation with as little as 2.7 grams of E 1.8 grams of DHA can markedly reduce the number of tender joints and increase the time before fa sets in. Arthritis patients who took fish oils could eliminate or sharply reduce their use of Non Steroi Anti-Inflammatory Drugs and other arthritis drugs.
Patients with ulcerative colitis have abnormally low blood levels of EPA. Clinical trials have shown th supplementation with fish oil (2.7 grams of EPA and 1.8 grams of DHA daily) can reduce the severit the condition by more than 50% and enable many patients to discontinue anti-inflammatory medica and steroids.
There is now also considerable evidence that fish oil consumption can delay or reduce tumor develo in breast cancer. Studies have also shown that a high blood level of omega-3 fatty acids combined v low level of omega-6 acids reduces the risk of developing breast cancer. Daily supplementation with little as 2.5 grams of fish oils has been found effective in preventing the progression from benign pc to colon cancer. Fish oil supplementation improves survival and quality of life in terminally ill cancer patients.

Safe and easily available
It is estimated that 85% or more of people in the Western world are deficient in omega-3 fatty acid most get far too much of the omega-6 fatty acids. Vegetarian diets, for example, tend to be very hi omega-6.
The recommended daily intake of EPA plus DHA is about 650 mg rising to 1000 mg/day during preg and lactation. Clinical trials have used anywhere from 1 g/day to 10 g/day, but little additional bene been observed at levels above 5 g/day of EPA and DHA combined. The benefits of therapeutic supplementation may become evident in a few weeks when blood parameters (triglycerides, fibrino are involved, but may take 3 months or longer to materialize in degenerative diseases like atherosc and rheumatoid arthritis.
Supplementing with fish oils has been found to be entirely safe even for periods as long as 7 years a significant adverse effects have been reported in hundreds of clinical trials using as much as 18

grams/day of fish oils. Fish oil supplementation does, however, lower blood concentrations of vitami it is a good idea to take extra vitamin E when adding fish oils to your diet. A clinical trial carried out the US Department of Agriculture found that taking 200 mg/day of synthetic vitamin E (equivalent t about 100 IU of natural alpha-tocopherol) is sufficient to completely counteract this effect of fish oil supplementation.

By Inna Nester

Active ingredients:

500 mg of concentrated marine fish oil, containing the following active substances:

EPA (eicosapentaenic acid) 18%, DHA (docosahexaenic acid) 12%

Dosage:

1 or 2 capsules three times daily

It should be administered in the form of cures (2 to 3 months). After a 2-3 month treatment period blood parameters should be controlled, and the continuation of the cure should depend on the results of the control tests

Contraindications:

Pregnancy and haemophilia

Storage:

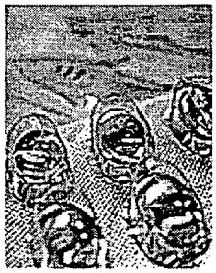
It should be stored at 15 to 25 grad C, protected from light and moisture

Presentation:

10 x 10 500 mg capsules

FISH OIL capsules

to buy her



Quality of Life Labs Neptune Krill Oil (NKO™) offers an exceptional antioxidant formula for women's health. It is clinically shown to manage emotional and physical PMS and Menopausal discomforts and to provide superior stability and safety.

Quality of Life Labs Neptune Krill Oil offers a significant source of phospholipids, powerful antioxidants and essential Omega-3 PUFAs (EPA and DHA). QOL-NKO is also a good source of choline, natural carotenoids, vitamin A and vitamin E and is non-oxidized with an excellent omega-6:omega-3 ratio.

Quality of Life Labs Neptune Krill Oil (NKO™) offers an exceptional antioxidant formula for women's health. It is clinically shown to manage emotional and physical PMS and Menopausal discomforts and to provide superior stability and safety.

Neptune Krill Oil

to buy her

More about unsaturated acids

Good Fat, Bad Fat: The Facts About Omega-3

Think all dietary fat is the same? Guess again

By Colette Bouchez
WebMD Weight Loss Clinic

Published Tuesday, July 27, 2004.
Reviewed By Kathleen Zelman, MPH, RD/LD

If you ask folks what food group they should avoid, most will probably answer "fats." While it's true that, in large amounts, some types of fat are bad for your health (not to mention your waistline), there are some we simply can't live without.

Among them are the omega-3 fatty acids, found in foods including walnuts, some fruits and vegetables, and coldwater fish such as herring, mackerel, sturgeon, and anchovies.

"It not only plays a vital role in the health of the membrane of every cell in our body, it also helps protect us from a number of key health threats," says Laurie Tansman, MS, RD, CDN, a nutritionist at Mount Sinai Medical Center in New York.

The benefits of omega-3s include reducing the risk of heart disease and stroke while helping to reduce symptoms of hypertension, depression, attention deficient disorder (ADD), joint pain and other rheumatoid problems, as well as certain skin ailments. Some research has even shown that omega-3s can boost the immune system

RESOURCE GUIDE

The Amazing Omega-3s
By Kathleen Zelman, MPH, RD

The jury is in: Omega-3 f acids have amazing heal

and help protect us from an array of illnesses including Alzheimer's disease.

Just how do omega-3s perform so many health "miracles" in people? One way, experts say, is by encouraging the production of body chemicals that help control inflammation -- in the joints, the bloodstream, and the tissues.

But even as important is their ability to reduce the negative impact of yet another essential type of fatty acid known as omega-6s. Found in foods such as eggs, poultry, cereals, vegetable oils, baked goods, and margarine, omega-6s are also considered essential. They support skin health, lower cholesterol, and help make our blood "sticky" so it is able to clot. But when omega-6s aren't balanced with sufficient amounts of omega-3s, problems can ensue.

"When blood is too 'sticky,' it promotes clot formation, and this can increase the risk of heart attack and stroke," says nutritionist Lona Sandon, RD, a spokeswoman for the American Dietetic Association. But once you add omega-3s to the mix, the risk of heart problems goes down, she tells WebMD.

properties, affecting ever from your joints to your heart. And a need to do is to enjoy a few serving week of omega-3-rich fish, nuts, se and oils.

Foods rich in omega-3s are also ex sources of lean protein -- which hel keep you feeling satisfied, making y less likely to overeat. So go ahead, yourself to your favorite seafood dis try one of the flaxseed recipes in thi article).

When you join the WebMD Weight Clinic, you'll get an eating plan that only helps you slim down but has al nutrients you need to keep feeling h strong, and energetic. Get started t

The latest research shows that the most promising health effects of essential fatty acic achieved through a proper balance between omega-3s and omega-6s. The ratio to sh experts say, is roughly 4 parts omega-3s to 1 part omega-6s.

Most of us, they say, come up dangerously short.

"The typical American diet has a ratio of around 20 to 1 -- 20 omega-6's to 1 omega-3 that spells trouble," says Sandon, an assistant professor of nutrition at University of Te Southwestern Medical Center in Dallas. While reducing your intake of omega-6s can h getting more omega-3s from food is an even better way to go.

How to Get What You Need

Omega-3 fatty acids are not one single nutrient, but a collection of several, including eicosapentaenic acid (EPA) and docosahexanoic acid (DHA). Both are found in greate abundance in coldwater fish -- and that, say experts, is one reason so many of us are deficient.

Over the past several years, the Food and Drug Administration and other groups have warnings about mercury and other harmful chemicals found in fish. This has led many to stop eating fish -- a big mistake, Tansman says.

"People have taken the whole FDA advisory out of context including who it's for, which primarily pregnant women, and small children," she says. Moreover, Tansman says, e you obey the FDA warnings in the strictest sense, the latest advisory says that up to 1 ounces of a variety of fish each week is safe for everyone. That amount, Tansman rem us, is roughly half of what we need to get enough omega-3s.

"The recommendation [for omega-3s] is two servings of fish a week," Tansman says. " 4 ounces per serving, that's well below the FDA's safe limit of 12 ounces per week."

According to the American Heart Association, those looking to protect their hearts sho a variety of types of fatty fish (such as salmon, tuna, and mackerel) at least twice a we Those with heart disease should get 1 gram of omega-3s (containing both EPA and DI day, preferably from fatty fish. About 1.5 ounces of fish contains 1 gram of omega-3s.

But even if you don't like fish (or choose not to eat it), you can still get what you need f dietary sources. WebMD Weight Loss Clinic "Recipe Doctor" Elaine Magee, MPH, RD one answer lies in plants rich in omega-3s -- particularly flaxseed.

"It's safe to say this is the most potent plant source of omega-3," says Magee, author c *Flax Cookbook*. While flaxseed contains no EPA or DHA, Magee says, it's a rich sourc another omega-3 known as alpha-linolenic acid (ALA), which the body can use to mak and DHA.

Flaxseed is available in health food stores and many supermarkets, sold as whole see ground seeds, or oil. Although flaxseed oil contains ALA, Magee says ground flaxseed much better choice because it also contains 3 grams of fiber per tablespoon, as well a healthy phytoestrogens. Other sources of omega-3s include canola oil, broccoli, canta kidney beans, spinach, grape leaves, Chinese cabbage, cauliflower, and walnuts.

"About an ounce -- or one handful -- of walnuts have about 2.5 grams of omega-3s," s Sandon. "That's equal to about 3.5 ounces of salmon."

Besides getting more omega-3s, you can also help your heart by replacing some ome from cooking oils with a third fatty acid known as omega-9 (oleonic acid). This is a monounsaturated fat found primarily in olive oil.

Though it is not considered "essential" (the body can make some omega-9), by substit for oils rich in omega-6s, you can help restore the balance between omega-3s and om 6s, plus gain some additional health benefits.

"Factors found in olive oil can also help boost the good cholesterol, which can also hel heart," says Magee.

Next page: Supplements vs. Foods ... ^ ba

1 | 2

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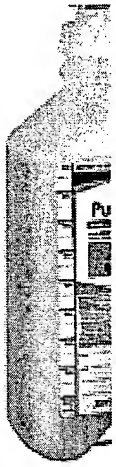
PRODUCT HANDBOOK

Pulmocare®
specialized nutrition for pulmonary patients



Usage Features Availability Administration Ingredients Protein Fat Carbohydrate Fit and Minerals Osmotic Concentration Renal Solute Load Analysis References Support Ma

Usage:
PULMOCARE is a low-carbohydrate formula specifically designed to help reduce carbon dioxid thereby minimizing CO_2 retention resulting from chronic obstructive pulmonary disease, cystic fi respiratory failure. PULMOCARE is appropriate for ambulatory or ventilator-dependent patients.

- For tube or oral feeding
- For supplemental or sole-source nutrition

Features:
- A source of complete and balanced nutrition
- Contains 20% of fat as medium-chain triglycerides (MCTs) to enhance fat absorption
- Meets or exceeds 100% of the DVs for 24 essential vitamins and minerals in 1420 Cal (947 r cans)
- Fortified with the antioxidants all-natural vitamin E, beta-carotene, and vitamin C
- Low-residue
- Lactose- and gluten-free
- Kosher

Caloric Distribution

	Per 8 fl oz	Per Liter	% Calories
Calories	355	1500	—

Protein, g	14.8	62.6	16.7
Fat, g	22.1	93.3	55.1
Carbohydrate, g	25.0	105.7	28.2
Water, g*	186	785	—

* 1 g water = 1 mL water = 1 cc water.

Availability:

Ready-To-Use 8-fl-oz cans; 24/case

Flavor	List Number
Vanilla	00699
Strawberry	50180

Ross Ready-To-Hang®
1000-mL prefilled containers; 8/case

Flavor	List Number
Unflavored	51204

See the Reimbursement section of Ross.com for third-party reimbursement information. The Re link can be found at the top of each page of Ross.com.

To order PULMOCARE by VISA®, MasterCard®, DISCOVER®, or check, please call 1-800-9 professionals and institutions should order in their usual manner.

Product information and values listed are subject to change. Please refer to product label or pac most current information.

Administration:

Use under medical supervision. Not for parenteral use.

Tube feeding: Follow physician's instructions. Adjust flow rate and volume according to patient's tolerance. Feed at room temperature. Minimum tube size for gravity feeding is 10 Fr; for pump f Additional fluid requirements should be met by giving water between or after feedings or when fl Avoid contamination during preparation and use.

Ross Ready -To-Hang®: Protect contents from light during storage. Hang product up to 48 hou spike when clean technique and only one new feeding set are used. Otherwise, hang no longer The availability of extended hangtime does not supersede your institution's policies, procedures practice guidelines. (See attached PDF at the top of this page. "Ross Ready-To-Hang® Sugges Procedure.")

Use by date on container.

Click Here To View Administration Schedule.

Ingredients:
Vanilla: [illegible]-D water, sodium and calcium caseinates, sugar (sucrose), canola oil, corn maltodext chain triglycerides, corn oil, high oleic safflower oil, magnesium chloride, calcium phosphate, so potassium citrate, natural and artificial flavors, sodium citrate, potassium phosphate, choline chl acid, carrageenan, taurine, L-carnitine, salt (sodium chloride), zinc sulfate, d-alpha-tocopheryl a sulfate, niacinamide, calcium pantothenate, manganese sulfate, cupric sulfate, thiamine chloride pyridoxine hydrochloride, riboflavin, beta-carotene, vitamin A palmitate, folic acid, biotin, chromi sodium molybdate, potassium iodide, sodium selenate, phylloquinone, cyanocobalamin and vita

Note: Vanilla and Strawberry flavors and Ready-To-Hang have similar compositions. For specif see product labels.

Protein:
The moderate protein level in PULMOCARE is designed to promote anabolism and the mainten body mass without excessively stimulating ventilatory drive.[1] Excessive protein intakes can be a patients with respiratory insufficiency and can be detrimental to the patient who is unable to resp increasing ventilation. Therefore, the protein content of PULMOCARE is designed to be adequa excessive, for the patient with ventilatory insufficiency.

The amino acid profile of the protein system in PULMOCARE meets or surpasses the standard profile for high-quality protein set by the National Academy of Sciences.[2]

Protein Profile

Percent of total calories from protein	16.7
Protein content	62.6 g/L

Protein Source

Sodium and calcium caseinates	100%

Cal/N ratio	150:1
Nonprotein Cal/N ratio	125:1

Fat:
The fat blend in PULMOCARE contains canola oil, MCTs, corn oil, high oleic safflower oil, and s

PULMOCARE provides the majority of calories from fat, which minimizes carbon dioxide produc increases caloric density. In respiratory insufficiency, the cardiopulmonary system is unable to r appropriately the oxygen and carbon dioxide levels in the blood. The primary defect is inability t carbon dioxide because ventilation of the lung is altered in relation to perfusion.

Since these patients suffer from carbon dioxide retention and oxygen depletion in the blood, the is to decrease the blood level of carbon dioxide. Administration of a diet with an increased propo calories and decreased carbohydrate calories can decrease carbon dioxide production and resp (RQ), thus diminishing ventilatory requirements. This effect occurs because of the differences in effects of fat and carbohydrate.

In the process of converting fat, carbohydrate, and protein to energy within the body, oxygen is carbon dioxide is produced. The ratio of carbon dioxide produced to oxygen consumed is the R produced from fat, carbohydrate, and protein are 0.7, 1.0, and 0.8, respectively. Metabolism of f lowest RQ; that is, the least carbon dioxide is produced for the amount of oxygen consumed. Th typical mixed diet is 0.85.[3]

Lowering carbon dioxide production by increasing dietary fat is desirable both for the patient wit obstructive pulmonary disease (COPD), for whom hypercapnia may exacerbate respiratory dist respiratory failure, and for the patient with respiratory failure who must be weaned from mechan

Fat Profile

Percent of total calories from fat	55.1

Total Fat	**93.3 g/L**
Polyunsaturated fatty acids	23.3 g/L
Monounsaturated fatty acids	38.7 g/L
Saturated fatty acids	24.9 g/L

Fat Source

Canola oil	56%
MCT oil	20%

Corn oil	14%
High oleic safflower oil	7%
Soy lecithin	3%

Cholesterol	<25 mg/L
Omega-6/omega-3 ratio	4:1

Carbohydrate:
The carbohydrate sources in PULMOCARE are sucrose and corn maltodextrin, both of which ar digested and absorbed. PULMOCARE is lactose-free and, therefore, can be consumed by lacto patients without adverse effects.

Nutrition support with a high-carbohydrate regimen results in an increase in carbon dioxide prod may be detrimental to the patient with pulmonary disease. High carbohydrate loads can precipit failure.[4,5] The administration of high-carbohydrate regimens to patients requiring mechanical ve impair the ability to wean.[6,7]

Although the body does not have a specific dietary carbohydrate requirement, a carbohydrate-fr to ketosis, excessive catabolism of tissue protein, and loss of fluid and electrolytes. These effec prevented by daily intake of 50 to 100 g of digestible carbohydrate if caloric intake is adequate.[8] is formulated with a level of carbohydrate (105.7 g/L) that can help prevent respiratory failure ca carbohydrate loads.

Carbohydrate Profile

Percent of total calories from carbohydrate	28.2
Carbohydrate content	105.7 g/L

Carbohydrate Source

Sucrose	54%
Corn maltodextrin	46%

Fiber:

Vitamins and Minerals:

PULMOCARE meets or exceeds 100% of the DVs for 24 essential vitamins and minerals in 142 or four 8-fl-oz cans.

Antioxidants
Lung injury by toxic levels of oxygen radicals is normally prevented by the presence of endogen within the epithelial lining fluid.[9] Much interest has been expressed in the antioxidant function of (vitamin E), ascorbic acid (vitamin C), and carotenoids. These antioxidants act as scavengers a potentially damaging reactions by eliminating pro-oxidants and free radicals.[10]

The all-natural form (R,R,R, stereoisomer; d-α-tocopherol) of vitamin E has been shown to be o bioavailability than synthetic isomers of vitamin E.[11] Therefore, it may be advantageous to feed natural vitamin E to maximize transport and replete deficient nervous system tissues.[12] PULMO 20 IU/8 fl oz or 85 IU/L of all-natural vitamin E.

Carotenoids function as antioxidants by quenching free radicals or O_2 in lipid phases. These an reactions are associated with lowering DNA damage, malignant transformation, and other parar and cell damage in vitro as well as epidemiologically, with lowered incidence of certain types of degenerative diseases.[10] Beta-carotene, a carotenoid compound, has provitamin A activity and naturally in the diet. PULMOCARE is fortified with 1.2 mg/8 fl oz (5.0 mg/L) of beta-carotene, wh

approximately 55% of the vitamin A activity in the product.

Although carnitine and taurine are present in low but adequate levels in a normal diet, these cor essential nutrients may become depleted during periods of metabolic stress.[13,14] Taurine has a properties important in controlling oxidative stress in metabolically stressed patients.[15] PULMO(supplemented with 36 mg/8 fl oz (160 mg/L) of taurine and carnitine.

Osmotic Concentration:
Osmotic concentration is influenced by caloric concentration, level and form of protein and carb level of electrolytes. Although calorically concentrated (1.5 Cal/mL), PULMOCARE has a moder because its carbohydrate level is low.

Osmolality (mOsm/kg H_2O)	475
Osmolarity (mOsm/L)	372

Renal Solute Load:
Renal solute load represents the solutes excreted per liter of product consumed. The major dete renal solute load are dietary protein and electrolytes. Each milliequivalent of sodium, potassium contributes approximately 1 mOsm to the renal solute load; in adults, each gram of protein conti approximately 5.7 mOsm.

Renal Solute Load (RSL)

	Electrolyte Content (mEq/L)	Contribution to RSL (mOsm/L)
Sodium	57.0	57.0
Potassium	50.1	50.1
Chloride	47.7	47.7
Protein content	62.6 g/L x 5.7 =	356.8
Total RSL		512

Analysis:

▼Nutrient Facts

	8 fl oz	1000 mL
FAN (label number)	7865-01	7677-03
Cal/mL	1.50	1.50
Energy, Cal	355	1500
Protein, g	14.8	62.6
% of total Calories	16.7	16.7
Fat, g	22.1	93.3
% of total Calories	55.1	55.1
Cholesterol, mg	5.9	<25
Carbohydrate, g	25	105.7
% of total Calories	28.2	28.2
Water, g*	186	785
Dietary Fiber, g	0	0
L-carnitine, mg	36	160
Taurine, mg	36	160

m-Inositol, mg		

* 1 g water = 1 mL water = 1 cc water.

Vitamins

	8 fl oz	1000 mL
Vitamin A, IU	2840	11910
Vitamin D, IU	100	425
Vitamin E, IU	20	85
Vitamin K, mcg	20	85
Vitamin C, mg	75	320
Folic Acid, mcg	200	850
Thiamin (Vitamin B1), mg	0.75	3.2
Riboflavin (Vitamin B2), mg	0.85	3.6
Vitamin B6, mg	1	4.3
Vitamin B12, mcg	3	13
Niacin, mg	10	43
Choline, mg	150	635
Biotin, mcg	150	635
Pantothenic Acid, mg	5	22

PULMOCARE includes 1590 IU/8 fl oz (6625 IU/L) of vitamin A activity supplied oz (5.0 mg/L) of beta-carotene.
Vitamin E is from an all-natural form (R,R,R-α-tocopherol).

Minerals

	8 fl oz	1000 mL
Sodium, mg (mEq)	310 (13.5)	1310 (57.0)
Potassium, mg (mEq)	465 (11.9)	1960 (50.1)
Chloride, mg (mEq)	400 (11.3)	1690 (47.7)
Calcium, mg	250	1060
Phosphorus, mg	250	1060
Magnesium, mg	100	425
Iodine, mcg	38	160
Manganese, mg	1.3	5.3
Copper, mg	0.5	2.2
Zinc, mg	5.7	24
Iron, mg	4.5	19
Selenium, mcg	18	74
Chromium, mcg	30	130
Molybdenum, mcg	38	160

Amino Acids

	8 fl oz	1000 mL

Essential		
Histidine, mg	400	1690
Isoleucine*, mg	696	2942
Leucine*, mg	1332	5634
Lysine, mg	1066	4507
Methionine, mg	414	1753
Phenylalanine, mg	740	3130
Threonine, mg	592	2504
Tryptophan, mg	163	689
Valine*, mg	873	3693
Nonessential		
Alanine, mg	429	1815
Arginine, mg	488	2066
Aspartic Acid, mg	1036	4382
Cystine, mg	59	250
Glutamic Acid, mg	3167	13396
Glycine, mg	266	1127
Proline, mg	1569	6636
Serine, mg	814	3443
Tyrosine, mg	725	3067

* Branched-chain amino acids.

▼Fatty Acids

	8 fl oz	1000 mL
Linoleic (18:2), mg	4367	18436
a-Linolenic (18:3), mg	1144	4831
Caprylic (8:0), mg	2729	10946
Capric (10:0), mg	1816	7667
Lauric (12:0), mg	52	222
Myristic (14:0), mg	31	133
Palmitic (16:0), mg	966	4077
Stearic (18:0), mg	357	1507
Oleic (18:1), mg	9164	38689
Arachidic (20:0), mg	84	355

Fatty acids equal approximately 95% of total fat.
Key for values in parentheses (carbon atoms:double bonds).

Other Values

Density at 23°C, g/mL	1.0534
pH	6.7
Osmolality, mosm/kg H2O	475
Osmolarity, mosm/L	372

Renal Solute Load, mosm/L	512
Cal to meet 100% RDIs	1420
mL to meet 100% RDIs	947
Total Cal/g nitrogen	150:1
Nonprotein Cal/g nitrogen	125:1

References:

Clinical Research

The beneficial effects of PULMOCARE when compared to standard enteral formulas have been in both ambulatory and ventilator-dependent patients with pulmonary disease.

High Fat Diets in COPD

A recent study by Cai et al[16] evaluated the effects of feeding a high-fat, low-carbohydrate (CHO (PULMOCARE) and a high-carbohydrate diet (60%-70% CHO, 20%-30% fat, 15% protein) in 6(patients with COPD with low body weight (<90% ideal body weight) for 3 weeks. Subjects in the group consumed two to three 8-oz servings of the high-fat, low-CHO oral supplement nightly (pr their estimated basal caloric needs), while subjects in the control group were instructed to consu diet from ordinary foods. Significant decreases (P<0.05) in RQ, carbon dioxide production (VCO consumption (VO_2), and minute ventilation (V_E) were measured in subjects consuming the high as compared with those consuming a high-CHO diet. Increases in forced expiratory volume (FE shown in both groups, but significant (P<0.05) only in the experimental group, thereby represent decrease in airway obstruction in the experimental group. The authors concluded that the high-f supplement was clinically effective in improving respiratory function in malnourished patients wit COPD.

Angelillo et al[17] studied the effects of PULMOCARE and two other enteral nutritional formulas in with chronic obstructive pulmonary disease (COPD) and hypercapnia. PULMOCARE was the hi calories), low-carbohydrate (28.2% of calories) formula. Additionally, a moderate-fat (30% of cal moderate-carbohydrate (53.3% of calories) formula and a low-fat (9.4% of calories), high-carbol of calories) formula were evaluated. The products were consumed as the sole source of nutritio randomized crossover design. PULMOCARE resulted in the lowest CO_2 production (VCO_2) and retention ($PaCO_2$) level. The RQ was significantly lower for this diet (0.87) than for the other die the nutritional support provided during the study resulted in significant increases in forced vital c and forced expired volume in 1 second (FEV_1).

In a study by Goldstein et al,[18] the effects of refeeding with a high-fat formula (PULMOCARE) o carbohydrate enteral formula (53% carbohydrate, 17% protein, 30% fat) were studied in malnou wtih COPD. Patients received enteral nutrition for approximately 20 days at approximately 1.7 ti resting energy expenditure (REE). PULMOCARE resulted in lower oxygen consumption and ca production than the high-carbohydrate formula. The metabolic response to each regimen was p to dietary content. Skeletal muscle function and endurance also improved during nutrition replet functional changes were primarily related to feeding duration.

Frankfort et al[19] fed five subjects with stable COPD one of three diets in a random order and m minute ventilation (V_E) and VCO_2 for 5 hours. The three diets were a water control feeding, 920 PULMOCARE, and 920 Cal of a high-carbohydrate, high-nitrogen enteral formula (HCN). Over t period, the HCN feeding caused a greater increase in both V_E and VCO_2 than PULMOCARE. D absorptive phase of the study (84 to 204 minutes following ingestion of the feeding), the HCN fe significantly higher (P < 0.05) increase in VCO_2 than the PULMOCARE feeding.

In another study, Frankfort et al[20] compared the effects of PULMOCARE to a 1.5 Cal/mL HCN e on exercise performance in subjects with chronic airflow obstruction (CAO). Twelve stable subje underwent incremental, symptom-limited exercise tests 90 minutes after ingesting 920 Cal of H(PULMOCARE, or a noncaloric placebo. Expired gases were collected continuously and analyze seconds.

The mean maximal workload after HCN was significantly less than after PULMOCARE or placel V_E at exhaustion was similar after HCN, PULMOCARE, and placebo. In comparison to placebo,

subjects had a decreased workload following HCN, while only 1 subject had a decrease in maxi workload following PULMOCARE.

These results suggest that meals with a higher fat and lower carbohydrate content may be less work performance of patients with CAO in the absorptive phase than meals with a lower fat and carbohydrate content. These findings may have clinical significance to patients with CAO who c postprandial exertion dyspnea.

Sklarek and associates[21] studied nine male subjects with COPD. In comparison to water intake increase in resting VCO_2 (22%) was significant ($P < 0.05$) after subjects ingested 355 Cal of an (ENSURE PLUS® HN), but not significant after subjects ingested 355 Cal of PULMOCARE (5% resting VCO_2). A high-fat diet may be useful in the management of subjects who become hypox during and after meals.

Goldstein et al[22] studied 8 malnourished patients with emphysema and 8 malnourished patients evidence of lung disease. Each patient received an infusion of 5% dextrose plus electrolytes for was then randomly assigned to a hypercaloric diet using a moderate-carbohydrate formula (MC PULMOCARE for the first week, maintaining a constant protein intake. The alternate diet was gi following week. Ventilation and gas exchange were measured using supine cycle ergometry dur dextrose, MC, and PULMOCARE diet periods.

The emphysema group demonstrated a 12% to 15% greater O_2 consumption, lower respiratory an O_2 debt greater than that of patients without evidence of lung disease. Resting ventilation we the MC than the PULMOCARE diet in both groups, but during the MC diet, patients with emphys more exaggerated ventilatory response. These results demonstrate that patients with emphyser unusual metabolic pattern during hypercaloric feeding and exercise. The PULMOCARE regimer to create more stress on the respiratory system during exercise than was generated with the MC

In a second study by Garfinkel et al,[23] 10 patients with severely impaired respiratory function we Seven of the patients required mechanical ventilatory support at the time of the study. The effec PULMOCARE and of standard enteral nutritional support on pulmonary function were evaluated function was improved with PULMOCARE. When compared to standard nutritional support, PUL resulted in decreases in VCO_2 from a mean of 269 to 205 mL/min and in $PaCO_2$ from 60.7 to 4(0.005). V_E and oxygen consumption were also significantly decreased.

In a study by Kuo et al,[24] the effects of PULMOCARE (high-fat) and ENSURE® (high-CHO) diet function and gas exchange were studied in COPD patients and normal subjects. In COPD patie CHO diet load vs PULMOCARE resulted in significantly higher levels of VCO_2, oxygen consump minute ventilation (V_E) and significantly lower levels of end-tidal CO_2. For those COPD patients longer increase their V_E to excrete CO_2, the ingestion of a high-CHO diet can be expected to im function and may lead to respiratory distress or failure. This study suggested that a high-fat diet beneficial to the COPD patient than a high-CHO diet.

High Fat Diets in Cystic Fibrosis

Kane et al[25] examined whether an increase in VCO_2 and ventilatory demands by carbohydrate different formulas during nighttime enteral feedings could be detrimental in young adults with cy moderate to advanced lung disease. Ten patients, age 17 to 24, received 1000 Cal/M^2 of PULM medium-carbohydrate (MC) formula, and a high-carbohydrate (HC) formula in random order.

Basal energy expenditure (BEE) without feedings averaged 120% of that predicted by the Harris equation. The metabolic expenditure by indirect calorimetry during nighttime feedings was 25% than the BEE. VO_2 increased 21% to 27% during nighttime feedings with no difference between VCO_2 increased 29% for PULMOCARE, 46% for MC, and 52% for HC. The increase in VCO_2 w PULMOCARE was significantly less than with MC ($P < 0.05$) and HC ($P < 0.005$). The RQ for PU (RQ = 0.88) was the same as the BEE, but increased with MC (RQ = 1.00) and HC (RQ = 1.08) increase in minute ventilation with HC was greater than the 25% to 28% increase observed with and MC ($P < 0.05$).

Nighttime enteral feedings in cystic fibrosis patients did not result in significant increased CO_2 re oxygen desaturation despite increased VCO_2, VO_2, minute ventilation, and metabolic expenditu PULMOCARE resulted in the lowest VCO_2, VO_2, and minute ventilation.

Kane and Hobbs[26] compared the influence of PULMOCARE and an HC nutritional supplement and pulmonary metabolism in 10 malnourished patients with cystic fibrosis with moderate to sev disease. Patients with cystic fibrosis have increasing difficulty maintaining their nutritional status pulmonary disease progresses, in part because of a 17% to 20% increase in their BEE. The pat

before ingesting the supplements was 120% of that predicted by the Harris-Benedict equation. production (VCO_2) increased 9% to 19% for the 3 hours after ingesting 500 Cal/M^2 of PULMOC to 30% after ingesting the HC supplement ($P < 0.05$). The RQ was significantly greater for HC t PULMOCARE. The minute ventilation rose 10% to 13% for the 3 hours after ingesting PULMOC 27% to 31% after ingesting the HC supplement, but the difference was not significant. The meta expenditure rose 13% to 16% for the 3 hours after ingesting both formulas. PULMOCARE resul VCO_2 and RQ than the HC supplement, suggesting that it is a reasonable nutritional supplemer with moderate to severe cystic fibrosis.

High Fat Enteral Nutrition and Ventilator Weaning

Al-Saady et al[27] prospectively compared the effects of PULMOCARE to a 1.5 Cal/mL high-carb enteral formula on $PaCO_2$ and ventilation time in patients with acute respiratory failure requiring ventilation. Twenty clinically stable patients requiring enteral feeding were randomized to receiv formula or PULMOCARE. Initial ventilator standard settings were adjusted according to clinical Measurements including minute volume and arterial blood gases were made twice daily. Weani out according to set criteria.

During the feeding period, $PaCO_2$ just prior to weaning fell by 16% in the PULMOCARE group, 4% in the HC group. The PULMOCARE group spent a mean of 62 hours less time on the ventil

Conclusion

These studies demonstrate that PULMOCARE is effective in decreasing carbon dioxide produc quotient, and carbon dioxide retention in patients with ventilatory insufficiency when compared t enteral formulas. Additionally, respiratory function improves with nutritional support.

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